UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,381,424 B2
APPLICATION NO. : 10/006740
DATED : June 3, 2008
INVENTOR(S) : Alexander MacGregor

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3, line 22, delete "therefore," and insert -- Therefore, --.

Column 8, line 1, delete "alpha." and insert -- α --;

Column 8, line 5, delete "17. alpha." and insert -- 17α --;

Column 8, line 6, delete "10. alpha." and insert -- 10α --;

Column 8, line 19, delete "beta." and insert -- β --;

Column 8, line 28, delete "B.sub. 12" and insert -- B_{12} --;

Column 8, line 38, delete "alpha." and insert -- α --;

Column 8, line 45, delete "carboxylicacid" and insert -- carboxylic acid --;

Column 8, line 55, delete "carboxylicacid" and insert -- carboxylic acid --; and

Column 8, line 61, delete "1 ,4" and insert -- 1,4 --.

Column 12, line 25, delete "Prefreably," and insert -- Preferably, --.

Column 16, line 33, delete "intrest" and insert -- interest --; and

Column 16, line 35, delete "interst" and insert -- interest --.

Column 18, delete lines 13 - 56 in their entirety; and

Column 18, line 66, delete "interestin" and insert -- interest in --.

Column 19, line 26, delete "Synamic" and insert -- Dynamic --;

Column 19, line 44, delete "orderto", and insert -- order to --;

Column 19, line 46, delete "swolien" and insert -- swollen --;

Column 19, line 52, delete "Materals" and insert -- Materials --;

Column 19, line 55, delete "Appaatus" and insert -- Apparatus --;

Column 19, line 61, delete "Merler-Taledo" and insert -- Mettler-Toledo --; and delete "forliquids" and insert -- for liquids --; and

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Column 19, line 67, delete "hydrodynaic" and insert -- hydrodynamic --.

Column 20, line 8, delete "This" and insert -- this --;

Column 20, line 9, delete "inerest" and insert -- interest --;

Column 20, line 17, after "over" insert the following: -- time wherein the influx of fluid is equal to the efflux of caffeine. This represents a controlled increase in the dynamic profile of a tablet, which reaches and maintains a maximum volume after a period of time (depending upon the ratio of the hydrodynamic fluid-imbibing polymer, to hydrostatic pressure modulating agent). Figure 4 shows the corresponding drug release (dissolution profile) for a formulation comprising a hydrostatic couple of the present invention, and displays a linear, zero-order release of an agent of interest for over 16 hours. Figures 2 and 4 demonstrate how the volume increase in a --.

Column 20, after line 17, insert the following paragraphs and table:

-- delivery system comprising a hydrostatic couple is reduced, resulting in an increased and continuous efflux rate. Because the rate of efflux of the agent of interest is independent on the concentration of the agent but dependent on the hydrostatic pressure within the delivery system, the kinetics of agent release is zero-order.

Examples 3-6:

In these examples hydrostatic delivery systems for extended release formulation of various therapeutic agents are presented. Two formulations (Formula 1 and Formula 2) are used to illustrate how the hydrostatic couple as described herein can be used to achieve zero-order kinetics and predictably different release rates. Formula 1 exhibits faster rates of drug release than that observed with Formula 2. The rate of release of the agent of interest may be selected considering several variables, for example, but not limited to the solubility of the agent of interest, and pharmacological activity of the

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agent of interest. For example, with decreased solubility of an agent of interest, faster release of the agent may be desired such as that provided by, but not limited to, Formula 1. In the case of a soluble agent of interest, slower release of the agent from the delivery system may be desired, for example, but not limited to, using a hydrostatic couple as provided in Formula 2. It is to be understood, however, that the formulation of the hydrostatic couple may be varied as required to obtain a desired rate of release of an agent of interest.

Example 3
Extended Release Theophylline 80 mg

Table 2

Extended Release Theophylline

Components	Formula-1	Formula-2
Theophylline USP	80.00 mg	80.00 mg
Carbopol 971P NF	320.00 mg	320.00 mg
Crospovidone XL-10	6.40 mg	0.00 mg
Crospovidone INF-10	0.00 mg	6.40 mg
Sodium Lauryl Sulphate NF	4.00 mg	4.00 mg
Colloidal Silicon Dioxide NF	3.00 mg	3.00 mg

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Column 21, line 23, delete "37 ⧺ C" and insert -- 37° C --.

Signed and Sealed this

Twenty-fourth Day of November, 2009

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office